



DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Part 355

[Docket No. FSIS-2020-0013]

RIN [0583-AD83]

Removal of 9 CFR 355- Certified Products for Dogs, Cats, and Other Carnivora; Inspection, Certification, and Identification as to Class, Quality, Quantity, and Condition

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is amending its regulations to end the program under which FSIS inspectors provide fee-for-service certification that certain foods for dogs, cats and other carnivora (pet food) are produced under sanitary conditions and meet compositional and labeling requirements. The certified pet food regulations are outdated, and no firms are paying for FSIS certification services for pet food. Further, the fact that both the United States Department of Agriculture (USDA) and the U.S. Food and Drug Administration (FDA) maintain regulations concerning pet food has led to industry and consumer confusion. Both agencies agreed that stakeholders will benefit from the simplification of Federal jurisdiction over pet food.

DATES: Effective [INSERT DATE 60 DAYS AFTER THE DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Rachel Edelstein, Assistant Administrator, Office of Policy and Program Development by telephone at (202) 205-0495.

SUPPLEMENTARY INFORMATION:

Background

On July 28, 2021, FSIS proposed to remove the certified pet food provisions (9 CFR part 355) from the regulations because they are outdated and no companies use the voluntary service. In addition, because FDA also maintains regulations concerning pet food, the FSIS regulations have led to industry and consumer confusion (86 FR 40369).

As FSIS explained in the proposed rule, under the Federal Food, Drug, and Cosmetic Act (FFDCA), FDA is responsible for ensuring that pet food is safe for animals, produced under sanitary conditions, contains no harmful substances, and is truthfully labeled. FDA has had authority to regulate pet food since the FFDCA was passed in 1938. FDA does not charge pet food producers a fee for any FDA activities related to pet food. Individual States also regulate and inspect pet food, which also minimizes the need for FSIS's program.

Since 1958, under the Agricultural Marketing Act (7 U.S.C. 1622(h)), USDA also provided for the voluntary certification of pet food as having been produced under sanitary conditions and meeting compositional and labeling requirements. Under the regulations at 9 CFR part 355, participating facilities pay for this certification. The regulations governing FSIS certification

services for pet food have not been substantively amended since the 1960s; therefore, the requirements are outdated (e.g., requirements regarding pet food ingredients and the submission of firm blueprints). Additionally, the regulations allow for certification of only certain categories of pet food (i.e., canned or semi-moist maintenance food, canned or fresh frozen certified supplemental animal foods, and canned certified variety meats). Many types of pet foods that were developed in the last few decades are thus not eligible for FSIS certification (e.g., pet jerky, pet treats, pet rawhides, raw pet food, freeze-dried pet food, and prescription pet food). Likely for these reasons, no firms are participating in the FSIS certified pet food program.

After considering the comments received on the proposed rule, discussed below, FSIS is finalizing the proposed rule without changes.

Summary of Comments and Responses

FSIS received 149 comments on the proposed rule from individuals and pet food industry groups. Below is a summary of the comments received and FSIS' responses.

Comments: FSIS received comments from several individuals and two industry groups that supported the removal of 9 CFR part 355. These commenters agreed that FSIS' voluntary pet food certification program is outdated and that having pet food under the jurisdiction of a single Federal agency will eliminate confusion by pet food consumers and manufacturers.

FSIS also received comments from pet food buyers and an industry group stating that FSIS should update its certified pet food program instead of removing it. The commenters suggested rewriting the regulation to remove obsolete references and updating the language to reflect more modern types of pet food.

Response: FSIS is not updating its certified pet food program because it would not be the best use of Agency resources. As noted above, no companies are currently participating in the FSIS certified pet food program, and FDA is responsible for ensuring that pet food is safe for animals, produced under sanitary conditions, contains no harmful substances, and is truthfully labeled.

Comments: Several individuals argued that FSIS should not remove its certified pet food program because they disagree with FDA's pet food inspection regulations. These individuals stated that FSIS' requirements are stricter than FDA's requirements.

Response: This final rule will not impact the safety of pet food products. As explained above and in the proposed rule (86 FR 40369), no firms are participating in FSIS' certified pet food program. Comments on FDA's regulation of pet food are outside the scope of this rulemaking.

Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including

potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This final rule has been designated as a "non-significant" regulatory action under section 3(f) of E.O. 12866. Accordingly, the rule has not been reviewed by the Office of Management and Budget (OMB) under E.O. 12866.

Expected Costs and Benefits of the Final Rule

This final rule clarifies that FDA has sole jurisdiction over pet food inspection, which benefits industry and consumers by reducing confusion. No firms are participating in the FSIS certified pet food program. Therefore, the final rule will not increase industry or Agency costs or have a negative impact on public health.

Regulatory Flexibility Act Assessment

The FSIS Administrator certifies that, for the purposes of the Regulatory Flexibility Act (5 U.S.C. 601-602), this final rule is not expected to increase costs to industry.

Paperwork Reduction Act

There are no new paperwork or recordkeeping requirements associated with this final rule under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

Executive Order 13175

This proposed rule will have no implications for Indian Tribal governments. More specifically, it does not have

substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes. Therefore, the consultation requirements of Executive Order 13175 do not apply.

Environmental Impact

Pursuant to the National Environmental Policy Act (42 U.S.C. 4321, et seq.) (NEPA), Federal agencies must prepare an environmental impact statement (EIS) for any "major Federal actions significantly affecting the quality of the human environment" (42 U.S.C. 4332(2)(C)). NEPA established the Council on Environmental Quality (CEQ), which promulgated regulations (40 CFR parts 1501-1508) to govern NEPA compliance. When a major Federal action is unlikely to have significant environmental effects or the significance of the effects is unknown, the Agency may prepare an environmental assessment (EA) (40 CFR 1501.3(a)(2), 1501.5) (2020). Federal agencies also may identify classes of actions that normally do not have significant environmental effects and therefore do not require the preparation of either an EA or EIS (40 CFR 1501.4(a)). Such classes of actions are "categorically excluded" from NEPA review unless extraordinary circumstances exist in which a normally excluded action may have a significant environmental effect (40 CFR 1501.3(a)(1), 1501.4)).

USDA's NEPA implementing regulations establish a categorical exclusion for specified categories of actions and

the actions of certain USDA agencies and agency units (7 CFR 1b.3, 1b.4). USDA has determined that the listed agencies, including FSIS (7 CFR 1b.4(b)(6)), "conduct programs and activities that have been found to have no individual or cumulative effect on the human environment" (7 CFR 1b.4(a)). Accordingly, all FSIS actions are categorically excluded from preparation of an EA or EIS unless the Agency head determines that a particular action may have a significant environmental effect (Id.). The action thus is categorically excluded unless FSIS anticipates that extraordinary circumstances from ending the certification program may have a significant environmental effect (7 CFR 1501.4(b)). This final rule, which removes 9 CFR 355 from the Code of Federal Regulations, will not create any extraordinary circumstances that will result in this normally excluded action having a significant effect on the human environment. Therefore, this action is appropriately subject to the categorical exclusion from the preparation of an environmental assessment or environmental impact statement provided under 7 CFR 1b.4 of the USDA regulations.

Executive Order 12988, Civil Justice Reform

This final rule has been reviewed under E.O. 12988, Civil Justice Reform. Under this rule: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) no administrative proceedings will be required before parties may file suit in court challenging this rule.

E-Government Act

FSIS and USDA are committed to achieving the purpose of the E-Government Act (44 U.S.C. 3601, *et seq.*) by, among other things, promoting the use of the internet and other information technologies and providing increased opportunities for citizens access to Government information and services, and for other purposes.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication on-line through the FSIS website located at: <https://www.fsis.usda.gov/policy/federal-register-rulemaking>.

FSIS also will make copies of this publication available through the FSIS *Constituent Update*, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The *Constituent Update* is available on the FSIS website. Through the website, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an email subscription service which provides automatic and customized access to selected food safety news and information. This service is available at: <https://www.fsis.usda.gov/subscribe>. Options range from recalls to export information, regulations, directives, and notices.

Customers can add or delete subscriptions themselves and have the option to password protect their accounts.

Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801, *et seq.*), the Office of Information and Regulatory Affairs has determined that this rule is not a "major rule," as defined by 5 U.S.C. 804(2).

USDA Non-Discrimination Statement

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List of Subjects in 9 CFR Part 355

Animal foods, Certified pet food, Labeling, Meat inspection, Packaging and containers, Reporting and recordkeeping.

PART 355—[REMOVED AND RESERVED]

For the reasons set out in the preamble, and under the authority of 7 U.S.C. 1622, 1624; 7 CFR 2.17 (g) and (i), and 2.55, FSIS removes 9 CFR part 355.

Done at Washington, DC.

Paul Kiecker,
Administrator.

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